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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/068,171	02/04/2002	Sally Mossman	014058-013300US	8073

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EXAMINER

BAHAR, MOJDEH

ART UNIT	PAPER NUMBER
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1617

DATE MAILED: 10/01/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/068,171

Applicant(s)

MOSSMAN ET AL.

Examiner

Mojdeh Bahar

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on 2/04/02
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-95 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 1-95 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____
- 4) ☐ Interview Summary (PTO-413) Paper No(s) _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

DETAILED ACTION

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 1-2 (in part), 7 (in part), 16-18 (1)¹ (all in part), 30-50 (all in part), 58-66 (all in part), 68 (in part), 3, 6, 8-12, 18 (2)-20, 28-29, and 69-72, drawn to a composition comprising an AGP where X is formula (Ia) and a saponin, classified in class 514, subclasses 449, 23, 32, for example.
- II. Claims 1-2 (in part), 7 (in part), 16-18 (1) (all in part), 30-50 (all in part), 58-66 (all in part), 68 (in part), 4, 73-76, a composition comprising an AGP where X is formula (Ib) and a saponin, classified in class 514, subclasses 460, 23, 32, for example.
- III. Claims 1-2 (in part), 7 (in part), 16-18 (1) (all in part), 30-50 (all in part), 58-66 (all in part), 68 (in part), 5, 13-15, 21-26, 77- 82, drawn to a composition comprising an AGP where X is formula (Ic) and a saponin, classified in class 514, subclasses 422,23, 32, for example.
- IV. Claims 1 (in part), 27, 83-86, drawn to a composition comprising a monophosphoryl Lipid A, and a saponin, classified in class 514, subclass 75, 23 and 32 for example.

¹ Note that there are two claim 18s. Examiner has referred to them as 18 (1) and 18 (2). Please note that appropriate correction is required to avoid confusion.

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- V. Claims 1 (in part), 51-57 and 67 drawn to a composition comprising a AGP, a saponin, and a virus or antigen classified in class 424, subclasses 184.1, 188.1, 189.1, 204.1, 207.1, 208.1, 206.1, for example.
- VI. Claims 87-89 (all in part), drawn to a method of treating cancer, infection and autoimmune diseases comprising administering and AGP where X is formula (Ia) and a saponin, classified in class 514, subclasses 449, 23, 32, for example.
- VII. Claims 87-89 (all in part), drawn to a method of treating cancer, infection and autoimmune diseases comprising administering and AGP where X is formula (Ib) and a saponin, classified in class 514, subclasses 460, 23, 32, for example.
- VIII. Claims 87-89 (all in part), drawn to a method of treating cancer, infection and autoimmune diseases comprising administering and AGP where X is formula (Ic) and a saponin, classified in class 514, subclasses 422, 23, 32, for example.
- IX. Claims 90-92 (all in part), drawn to a method of enhancing the immune response comprising administering and AGP where X is formula (Ia) and a saponin, classified in class 514, subclasses 449, 23, 32, for example.
- X. Claims 90-92 (all in part), drawn to a method of enhancing the immune response comprising administering and AGP where X is formula (Ib) and a saponin, classified in class 514, subclasses 460, 23, 32, for example.
- XI. Claims 90-92 (all in part), drawn to a method of enhancing the immune response comprising administering and AGP where X is formula (Ic) and a saponin, classified in class 514, subclasses 422, 23, 32, for example.

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- XII. Claims 93-95 (all in part), drawn to a method of enhancing the immune response comprising administering and AGP where X is formula (Ia) an antigen and a saponin, classified in class 514, subclasses 449, 23, 32, for example.
- XIII. Claims 93-95 (all in part), drawn to a method of enhancing the immune response comprising administering and AGP where X is formula (Ib), an antigen and a saponin, classified in class 514, subclasses 460, 23, 32, for example.
- XIV. Claims 93-95 (all in part), drawn to a method of enhancing the immune response comprising administering and AGP where X is formula (Ic), an antigen and a saponin, classified in class 514, subclasses 422, 23, 32, for example.

Inventions I with VI and IX; II with VII and X; III with VII and XI; V with XII-XIV are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case)). In the instant case rheumatoid arthritis, an autoimmune disease can be treated by COX-II inhibitors, cancer can be treated with chemotherapeutic agents and radiation, infections can be treated with antibiotics, the immune system could be boosted by employing zinc or other immune booster compounds.

.Inventions I-V are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions different modes of operation.

Inventions VI-XIV are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions Groups VI-VIII have a different function than Groups IX-XIV. Further each of the groups IX-XVI have a different mode of operation.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

Applicant is advised that in order for the reply to this requirement to be complete it must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Because the above restriction/election requirement is complex, a telephone call to the applicant's agent to request an oral election was not made. See M.P.E.P. Sec 812.01.

Specie Election

Claims 1-95 are generic to a plurality of disclosed patentably distinct species comprising

- Antigens

- Saponins
- AGPs

The claims as presented contain such vast multitude of “possibilities and permutations” for different species of each of the above therapeutic agents and possible combinations of these species in the instant compositions and methods that the search for all is considered an undue burden on the office. The search for all species and all possible combinations constitutes a burden to the office. Note that search is not limited to patent files.

Applicant is required to elect a specific specie (i.e., one single compound) for each of the above three active agents for examination purposes (i.e., antigen, AGP and saponin). A specific specie is a compound wherein all the substituents are clearly defined. Applicant is advised that the response to this requirement must include an identification of the species that is consonant with the requirement set forth in 35 U.S.C. 121 as well as a listing of all claims readable thereon.

Claims 87-89 are generic to a plurality of disclosed patentably distinct species comprising cancer, autoimmune diseases, and infection. **Applicant is required under 35 U.S.C. 121 to elect a single disclosed species, even though this requirement is traversed.** The treatment of each of these broad classes of diseases represents a separate field of medical technology having a separate field of search. The search for the treatment of all of these classes of diseases is therefore an undue burden on the office. Note that the search is not limited to the patent files. Applicant is required to elect one single class of diseases, e.g., cancer for examination purposes.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

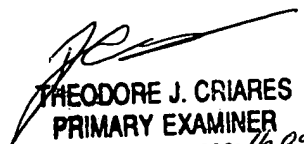
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mojdeh Bahar whose telephone number is (703) 305-1007. The examiner can normally be reached on (703) 305-1007 from Monday to Friday from 9:00 a.m. to 5:00 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreeni Padmanabhan., can be reached on (703) 305-1877. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-4556.

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Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.

Mojdeh Bahar
Patent Examiner
September 25, 2003


THEODORE J. CRIARES
PRIMARY EXAMINER
GROUP 1200/600